

REMARKS

Applicants respectfully request entry of the above amendments to the claims, and reconsideration of the application in light of the amendments to the claims and the arguments presented below.

The pending claims are set forth above. Claims 38, 41, 43 and 44, as herein amended, and claims 45, 46 and 48, as filed are pending in this application. Claims 1-37, 39, 40, 42, 47 and 49-68 have been cancelled without prejudice or disclaimer. Support for the amendments presented herein can be found, *inter alia*, in the specification on p. 30, paragraph 1 and in Tables 1 and 2.

The amendments to the pending claims are made without prejudice or disclaimer, and are fully supported by the specification as filed. No new matter has been added as a result of the above amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

Applicants have amended the instant specification to remove the embedded hyperlink, and submit herewith a revised sequence listing containing the sequence identified in the Action as falling within the scope of 37 C.F.R. §1.821 *et seq.* This sequence listing is submitted in computer-readable and paper format, which are identical.

Claims rejections under 35 USC § 112, first paragraph (written description)

The Office maintains the previously-asserted rejection of claims 38, 41, 43-46 and 48 under 35 USC § 112, first paragraph, for not providing a written description of the invention so as to reasonably convey to one of skill in the art that the inventor(s), at the time the application was filed, had possession of the invention. The Action asserts that Applicants' earlier-presented argument has been considered but was not persuasive.

As an initial matter, Applicants have amended claims 38 and 43 to recite a fragment consisting of the sequence of amino acid residues from 101-121, rather than 101-151, of SEQ ID NO: 243. Applicants' representative thanks the Examiner for pointing out this typographical error.

Applicants disagree with the assertion made in the Action that the specification fails to teach structure or relevant identifying characteristics of a representative number of fragments of SEQ ID NO: 243. However, to expedite prosecution of the pending claims to allowance, Applicants have amended the claims to recite specifically-disclosed antigenic peptide fragments identified with reference to specific amino acids of an explicitly-disclosed polypeptide identified

by SEQ ID NO: 243. Applicants have also amended their claim to recite that each of these explicitly-recited fragments comprises an antigenic epitope that is capable of causing an immunological response in a human, wherein the fragments "consist of" the amino acid sequence disclosed in the specification. Applicants believe these amendments are sufficient to overcome the asserted grounds of rejection.

In light of Applicants explicit disclosure in their specification, and the amendments submitted herewith, Applicants believe that the rejection under 35 USC § 112, first paragraph has been overcome. They therefore respectfully request the Patent Office to reconsider and withdraw these grounds of rejection.

Claims rejections under 35 USC § 112, first paragraph (enablement)

The Office further maintains the previously-asserted rejection of claims 38, 40, 41, 43-46 and 48 under 35 USC §112, first paragraph, for failing to provide an enabling disclosure. The basis for the continued maintenance of this ground of rejection is that the inclusion of "fragments, variants, analogs or homologs" would constitute undue experimentation. The Action cites scientific journal articles to the effect that the change in a single amino acid could unpredictably alter the immunospecificity and binding between the antigenic peptides of the invention and hyperimmune reactive sera. Thus, the Action concludes, determining the alterations that so affect immunospecificity would constitute undue experimentation.

Applicants argued in response to the previous assertion of this ground of rejection that the amount of experimentation would not be undue, in view of the disclosure in their specification. Applicants asserted that the specification provides clear guidance to one of skill in the art for making the explicitly-recited antigenic peptide fragments of the polypeptide of SEQ ID NO: 243 and demonstrates immune response thereto. The Office remained unconvinced, asserting that the specification is enabling only for antigens "comprising the amino acid sequence [of] SEQ ID NO: 243, an antigenic peptide fragment consisting of amino acids 1-285 of the amino acid sequence [of] SEQ ID NO: 243, [and] antigenic peptide fragment[s] consisting of amino acids 15-37, 32-57, 101-121, 115-135, 138-158, 152-172, 220-242, or 236-258 of SEQ ID NO: 243." While not acquiescing to the assertions set forth in the Action, and solely to expedite prosecution of the pending claims to allowance, Applicants have amended the claims to recite specifically-disclosed antigenic peptide fragments identified with reference to specific amino acids of an explicitly-disclosed polypeptide identified by SEQ ID NO: 243. Applicants have also amended their claim to recite that each of these explicitly-recited fragments

comprises an antigenic epitope that is capable of causing an immunological response in a human, wherein the fragments "consist of" the amino acid sequence disclosed in the specification. Applicants believe these amendments are sufficient to overcome the asserted grounds of rejection.

Based on this disclosure, Applicants respectfully submit that the specification provides enablement for their invention as instantly claimed throughout their entire scope, and that one of skill in art would not exercise undue experimentation to make or use the claimed invention. Accordingly, Applicants respectfully request that the Examiner withdraw this ground of rejection.

Claims rejections under 35 USC § 102

Claims 38, 40 (cancelled herein), 41, 42 (cancelled herein), 43-45 and 48 stand rejected under 35 USC §102(b) as being anticipated by Massignani et al. (WO 02/077021). The Office asserts that the Massignani reference discloses an isolated *S. pneumoniae* antigen with SEQ ID NO: 4652 that is 100% identical to the claimed SEQ ID NO: 243, along with pharmaceutical compositions comprising therapeutic amount of peptide SEQ ID NO: 4652.

Applicants respectfully disagree with the Action's interpretation of the disclosure of the Massignani reference. However, to expedite prosecution of the pending claims to allowance, Applicants have amended the claims to recite specifically-disclosed antigenic peptide fragments identified with reference to specific amino acids of an explicitly-disclosed polypeptide identified by SEQ ID NO: 243. Applicants have also amended their claim to recite that each of these explicitly-recited fragments comprises an antigenic epitope that is capable of causing an immunological response in a human, wherein the fragments "consist of" the amino acid sequence disclosed in the specification. Applicants believe these amendments are sufficient to overcome the asserted grounds of rejection.

Applicants respectfully submit that the Massignani reference does not anticipate their claims as herein amended, and respectfully request that the Office withdraw this ground of rejection.

CONCLUSION

Applicants respectfully contend that the instant application is in condition for allowance in view of the claim amendments and arguments presented above, and respectfully requests that the claims as set forth herein be allowed.

If the Examiner believes that a telephone or personal interview would expedite prosecution of the instant application, the Examiner is respectfully invited to call the undersigned attorney at (312) 913-0001.

Respectfully submitted,
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